In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-660V

UNPUBLISHED

JUDY WELCH, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: November 18, 2020 Special Processing Unit (SPU); Findings of Fact; Onset and Site of Vaccination; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Shealene Priscilla Mancuso, Muller Brazil, LLP, Dresher, PA, for petitioner.

Sarah Black Rifkin, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT[1]

On May 10, 2018, Judy Welch filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered a Table shoulder injury related to vaccine administration ("SIRVA") resulting from the adverse effects of the influenza ("flu") vaccine she received on August 31, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons discussed below, I find the flu vaccine alleged as causal was administered in Petitioner's right deltoid; that her pain and reduced range of motion were

[1] Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

limited to the shoulder in which the intramuscular vaccine was administered; and that the onset of Petitioner's SIRVA-related pain occurred within 48 hours of vaccination.

I. Relevant Procedural History

Ms. Welch filed her petition for compensation on May 10, 2018. ECF No. 1. Petitioner filed relevant medical records and a Statement of Completion by May 15, 2018. On April 1, 2019, Respondent filed a status report indicating that he was not able to engage in settlement discussions at that time, and requesting 60 days to file a Rule 4(c) Report. ECF No. 18.

On July 8, 2019, Respondent filed his Rule 4(c) Report recommending that entitlement to compensation be denied under the terms of the Vaccine Act. Respondent's Report at 1. ECF No. 22. Respondent argued that the contemporaneous records established the the vaccine was administered in Petitioner's left deltoid – not her right shoulder as alleged. *Id*. at 4-5. Additionally, Respondent asserted that Petitioner did not seek treatment for right shoulder pain until nearly four months after her vaccination, which "is well outside a medically appropriate interval to ascribe causation to immunization." *Id*. at 7. Finally, Respondent maintained that the Table criterion that pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered has not been met, "given that [P]etitioner's vaccination record lists her left arm as the site of administration." *Id*. at 6-7.

In a Scheduling Order filed on November 14, 2019, I expressed my view that based on review of the existing record, a hearing would not be necessary, and that I intended to issue a fact finding as to the onset of Petitioner's alleged injury, the site of vaccine administration, and limitation of Petitioner's range of motion after providing the parties an opportunity to file briefs and any evidence they wish to have considered. ECF No. 26. On December 16, 2019, Petitioner filed a Motion for a Ruling on the Record. ECF No. 27. On January 14, 2020, Respondent filed a response brief. ECF No. 29. On January 21, 2020, Petitioner filed a reply to Respondent's response brief. ECF No. 30. The matter is now ripe for adjudication.

II. Issue

The following issues are contested: whether (1) Petitioner received the vaccine alleged as causal in her right arm; (2) Petitioner's pain and reduced range of motion were limited to the shoulder in which the intramuscular vaccine was administered; and (3) Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii)-(iii) (required onset for pain listed in the QAI; pain and range of motion limited to vaccinated arm requirement).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 3(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

A. *Site of Vaccination*

Based upon a review of the entire record, I find that Petitioner's August 31, 2016 flu vaccine was likely administered in her right arm, as she contends. Specifically, I base my finding on the following evidence:

- At Petitioner's initial treatment visit with her primary care physician on December 19, 2016, she complained of right arm pain "since she had her flu shot on 8/31/2016." Ex. 2 at 8

- Petitioner had a follow-up visit with her primary care physician on February 27, 2017. Petitioner's history of present illness states Petitioner as having right arm pain since August, which "improved after she had the injection but it came back and feels like an ache." Ex. 2 at 7

- On March 13, 2017, Petitioner had an appointment with an orthopedist. The orthopedist noted that Petitioner "had a flu vaccination in August of 2016- the injection was given into her right shoulder and she's noted increased right shoulder pain since that time." Ex. 4 at 4.

- Petitioner had an initial physical therapy (PT) evaluation on March 22, 2017. At this visit, Petitioner reported that "she has had progressive right shoulder/arm pain since a flu injection in August, 2016" and she complained of "transient, but daily right shoulder/arm pain rated at 8/10." Ex. 5 at 13.

- On April 13, 2017, Petitioner had a follow-up visit with Petitioner's orthopedist. Petitioner's "Chief Complaint" was "Right Shoulder Follow Up." The orthopedist documented, "64 year-old left-hand-dominant white female returns to the office today-[s]he had an injection-flu vaccination back in August of 2016 and unfortunately has continued right shoulder/deltoid pain since that injection." Ex. 2 at 3. This record confirms that Petitioner is left hand dominant. *Id*.

- On July 6, 2017, Petitioner had a right shoulder MRI with contrast. The MRI revealed "1. There is essentially full-thickness slightly retracted rotator cuff tear at the distal insertional articular surface fibers of the mid through posterior. 2. Amorphous intrasubstance superior labral tear. 3. Mild to moderate intra-articular biceps tendinosis with extraarticular tenosynovitis." Ex. 6 at 1-2

The above-referenced evidence supports a finding that Petitioner's August 31, 2016 vaccine was likely administered in her right shoulder. In the context of seeking care, Petitioner consistently reported that the vaccine had been administered in her right arm, and that the injury was associated with the vaccination. Accordingly, there is record support for her contention about the situs of administration, beyond her own allegations. Although there was some delay from the August 2016 vaccination to the first doctor's visit when right arm pain was discussed in December 2016, there are no intervening records that would contradict the situs conclusion.

In addition, Petitioner's physician has provided a logical explanation for why the vaccine would likely have been administered in her right arm. In her affidavit, Petitioner asserts that she requested that the flu vaccine be administered in her "non-dominant right arm." Ex. 8 at 1. On December 21, 2017 (several months before this case was initiated), Petitioner visited her physician "to have a correction on the documentation that was entered regarding her flu vaccine in 2016. She states that it was administered in her right arm but was charted here as in the left arm [s]he has ongoing pain in the right arm and wants something in writing to states this was an error." As Petitioner's physician further explained:

> "We had a significant discussion with the patient stating that documentation is stating that it was done in the left shoulder. Unfortunately all of her subsequent visits reference the right shoulder as the site where she had her flu shot. We discussed with her the possibilities for this discrepancy. The most likely explanation is that as is standard policy developed in our office, all flu shots are given in the left arm. This helps standardize the documentation when we are giving upwards to 30 or 40 shots a day to patients. If the shot were given in the other arm it would be not a routine procedure. Therefore there would be the possibility that it could be documented as the standard left side. In discussing with the patient she

> does remember requesting this shot be given in her right arm because she is left handed. This would make logical sense. Based on the fact that all of the subsequent visits referenced the right arm in relation to her flu shot, it would seem reasonable that that was the explanation for the discrepancy in the documentation."

Ex. 2 at 3. Thus, in effect the documented situs was a product of general office policy, rather than a reflection of what actually occurred, This explanation is also consistent with the medical records documenting that Petitioner is left hand dominant, and therefore reasonably did not want the vaccine administered there despite office policy.

I acknowledge that the vaccine administration record *itself* memorializes administration of the flu vaccine in Petitioner's left deltoid. Ex. 1 at 2. However, all other medical records support a finding that the vaccine was actually administered in Petitioner's right arm, and the statements of Petitioner and her physician amplify reasons to find the latter conclusion persuasive. I therefore find it more likely than not that the vaccination alleged as causal in this case was administered to Petitioner in the right arm/shoulder on August 31, 2016.

B. *Pain and Reduced Range of Motion Limited to Right Arm*

Based upon a review of the entire record, I find that Petitioner's pain and reduced range of motion were limited to her right shoulder. In the Respondent's Report, Respondent asserts that Petitioner's "pain and reduced range of motion" were not "limited to the shoulder in which the intramuscular vaccine was administered" given that Petitioner's vaccination record lists her left arm as the site of administration. Respondent's Report at 6-7 *citing* 42 C.F.R. § 100.3(c)(10)(iii). However, in his brief, Respondent avers that Petitioner did not "address the factual issue of whether she displayed limitations in her range of motion, likely because her range of motion has consistently been normal." Resp. at 8.

Respondent advances two distinct arguments in the Respondent's Report and in is his response brief, respectively. The first argument is that Petitioner's pain was not limited to the shoulder in which Petitioner received the vaccine. Respondent's Report at 6-7. This argument, however, was predicated on acceptance of Respondent's contention that Petitioner received the vaccine in her left shoulder. Based on my finding herein, that argument is moot.

Respondent's second argument is that Petitioner did not have reduced range of motion. Resp. at 8. In response, Petitioner asserts that "Respondent ignored Petitioner's physical therapy records which indicate decreased range of motion and later improvement as a result of physical therapy treatment." Reply at 5. Petitioner notes PT

records which indicate goals of improved range of motion, as well as noting that after PT concluded, Petitioner's range of motion had increased. *Id*. *citing* Ex. 5 at 6, 13. Petitioner has the better of this fact argument. Although at times Petitioner is noted to have full range of motion in her right shoulder, there are several instances where her right shoulder pain and stiffness are mentioned, in addition to references to exercises and goals to increase Petitioner's range of motion. *See* Ex. 2 at 3, 6; Ex. 5 at 13. The degree of reduced range of motion may bear on the damages Petitioner should receive (as her SIRVA may be less severe than other cases), but there is sufficient evidence of reduced range of motion in the record to decide this issue for Petitioner.

C. *Onset*

Based upon a review of the entire record, I find that the onset of Petitioner's pain occurred within 48 hours. Specifically, I base my finding on the following evidence:

- Petitioner was administered a flu vaccine in her right deltoid on August 31, 2016. Ex. 1 at 3; *See* discussion *supra* Part IV.A.

- In her affidavit, Petitioner stated that at the time of vaccine administration, the administrator of the shot was standing, and she was sitting. Ex. 8 at 1. Petitioner asserted the evening of her vaccination she "felt a soreness and a lingering ache at the site of the injection." *Id*. Petitioner described the "effect of the shot as being progressive. It began at the site of the injection, becoming more severe and noticeable in [her] right shoulder." *Id*.

- On December 19, 2017, three months and nineteen days after vaccination, Petitioner presented to her primary care physician, with a complaint of "right ar[m] hurting since she had her flu shot on 8/31/16. She states that it felt like an ache but there was no redness, swelling or itching. The ache just did not go away. She has never had this before with the flu shot." Ex. 2 at 10. Petitioner's symptoms were noted as "an off-and-on discomfort . . . . [i]t is distinctly related to the timing of her flu shot." *Id*.

- In a follow-up visit with her primary care physician on February 27, 2017, the physician indicated, "Patient is still having [right] arm pain since [A]ugust. She states it improved after she had the injection but it came back and feels like an ache." *Id*. at 7. Petitioner's diagnosis was pain in right shoulder secondary to flu shot 12/16. *Id*. at 8. Petitioner was referred to orthopedics. *Id*.

- On March 13, 2017, Petitioner presented to her orthopedist. Ex. 4 at 4. The orthopedist noted that Petitioner "had a flu vaccination in August of 2016-the injection was given into her right shoulder and she's noted increased right shoulder pain since that time." *Id*.

- Petitioner underwent a PT evaluation on March 22, 2017. Ex. 5 at 13. The physical therapist reported that "she has had progressive right shoulder/arm pain since a flu injection in August, 2016. *Id*. Petitioner complained of transient, but daily right shoulder/arm pain rated at 8/10. *Id*.

- On April 13, 2017, Petitioner had a follow-up visit with Petitioner's orthopedist. Petitioner's "Chief Complaint" was "Right Shoulder Follow Up." The orthopedist documented, "64 year-old left-hand-dominant white female returns to the office today-[s]he had an injection-flu vaccination back in August of 2016 and unfortunately has continued right shoulder/deltoid pain since that injection." Ex. 2 at 3.

- Petitioner's son, Sirius Welch, submitted an affidavit dated September 17, 2019, in which he recalled Petitioner "complaining of pains in her right arm from her vaccination earlier that day." Ex. 9 at 1. Although Mr. Welch did not recall the exact day he spoke to Petitioner, he did recall that it was the week before Labor Day and was in 2016. *Id*. Mr. Welch indicated that Petitioner is not the type of person to complain about pain, so when she did complain, "it seemed reasonable to conclude that these pains must have been severe enough for her to mention them out loud." *Id*.

The above items of evidence collectively establish that Petitioner's shoulder pain most likely began within 48 hours of receiving the August 31, 2016 flu vaccine. I recognize that Petitioner's medical records do not reflect a precise date of onset, and also that the vague temporal references to onset (i.e., "*after* receiving a flu shot . . .") allow for the possibility that onset occurred more than 48 hours from vaccination. However, there is no counterevidence undercutting Petitioner's contention that her pain began close-in-time to vaccination, and she consistently attributed her shoulder symptoms to her flu shot.

Admittedly, there is evidence of an intervening medical appointment, but I do not find that it rebuts this onset conclusion. Petitioner had one intervening appointment on October 4, 2016, where she complained of great toe pain. Ex. 2 at 12. Petitioner explained that she did not disclose her right shoulder pain at this visit because her "primary care doctor requests a single medical concern per appointment. In fact, he has a sign on the patient room's wall to this effect." Ex. 8 at 1; Mot. at 2 n. 1. Respondent contends that there is no evidence to support this assertion, and that this is inconsistent with some of Petitioner's other encounters with her primary care physician. *See* Resp. at 7. Although Respondent's point is reasonable, a single intervening medical encounter where only one issue was addressed is not enough to disprove onset, especially given the overwhelmingly consistent assertions at all subsequent medical encounters. Furthermore, the affidavits submitted by Petitioner and her witness are consistent with the medical evidence, and I have found no reason not to deem them credible otherwise.

I also do not conclude that Petitioner's treatment delay undermines her onset assertions. Petitioner's medical records and affidavits reflect a pattern similar to other SIRVA claims, in which injured parties reasonably delay treatment, often based on the assumption that their pain is likely transitory. *See, e.g., Tenneson v. Sec'y of Health & Human Servs*., No. 16-1664V, 2018 WL 3083140, at *5 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *mot. for review denied,* 142 Fed. Cl. 329 (2019), (finding a 48-hour onset of shoulder pain despite a nearly six-month delay in seeking treatment); *Williams v. Sec'y of Health & Human Servs*., 17-830V, 2019 WL 1040410, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 2019) (noting a delay in seeking treatment for five-and-a-half months because petitioner underestimated the severity of her shoulder injury); *Knauss v. Sec'y of Health & Human Servs*., 16-1372V, 2018 WL 3432906 (Fed. Cl. Spec. Mstr. May 23, 2018) (noting a three-month delay in seeking treatment). Here, the temporal delay is not lengthy enough to cast doubt on a shorter onset.

Finally, Respondent maintains that the medical records do not corroborate Petitioner's argument that her pain began as a soreness and ache at the site of injection on the evening of the vaccination, and then progressed becoming more severe and noticeable, but rather reveal only "off-and-on discomfort." Resp. at 8 *citing* Mot. at 8; Ex. 2 at 10; Ex. 8. I find, however, that the record is consistent with Petitioner's contention. At her initial appointment, Petitioner described her initial pain as an ache, and that "the ache just did not go away." Ex. 2 at 10. Then, at her February 27, 2017 appointment, Petitioner again noted the onset of her pain to be in August 2016, which had improved "but it came back and feels like an ache." *Id*. at 7. In her other follow-up appointments with the orthopedist, and at the initial PT evaluation, Petitioner also described her symptoms as progressive and increasing. *See* Ex. 4 at 4 *and* Ex. 5 at 13. And Petitioner described her pain as transient, but daily. Ex. 5 at 13. Therefore, I find it credible that the onset of Petitioner's pain was as she described, beginning as a soreness and aching, but also that it persisted and progressed, rather than waxing and waning.

Accordingly, I find there is preponderant evidence to establish that the onset of Petitioner's left shoulder pain occurred within 48 hours of the August 31, 2016 flu vaccination.

V. Conclusion

In light of all of the above and after a review of the record as a whole, I find that (1) the August 31, 2016 flu vaccine was likely administered into Petitioner's right arm; (2) Petitioner's pain and reduced range of motion were limited to the shoulder/arm in which the intramuscular vaccine was administered; and (3) that the onset of petitioner's shoulder pain occurred within 48 hours of her vaccination.

VI. Scheduling Order

Given my finding of fact regarding onset – and specifically that it is consistent with the Table requirements for a SIRVA claim - Respondent should evaluate and provide his current position regarding the merits of Petitioner's case.

Respondent shall file, by no later than **Monday, January 18, 2021**, an amended Rule 4(c) Report reflecting Respondent's position in light of the above fact-finding.

Any questions about this order or about this case may be directed to OSM staff attorney **Reiko Suber at (202) 357-6378 or Reiko_Suber@cfc.uscourts.gov.**

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master